Life Goals Collaborative Care for Patients With Bipolar Disorder and Cardiovascular Disease Risk

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Randomized Controlled Pilot Study of Life Goals Collaborative Care for Patients with Bipolar Disorder and Cardiovascular Disease Risk from Community-based Practices

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Abstract

Objectives—The goal of this randomized controlled pilot study was to determine whether Life Goals Collaborative Care (LGCC) compared to enhanced treatment as usual, reduced cardiometabolic factors and improved outcomes for persons with bipolar disorder from community-based practices.

Methods—Persons were randomized to receive LGCC (N=32) or enhanced treatment as usual (N=33). LGCC included four weekly self-management sessions and telephone contacts to encourage provider engagement and measurement-based care; enhanced treatment as usual included wellness mailings. Outcomes were body mass index-BMI, blood pressure, quality of life, functioning, and symptoms.

Results—Compared to enhanced treatment as usual, LGCC was not associated with reduced cardiometabolic risk factors based on 6 and 12-month repeated measures analyses. Among patients with BMI >=30 or systolic blood pressure >=140, LGCC was associated with decreased impaired functioning (respectively beta=−2.2, beta=−3.8;p=.04 for both) and depressive symptom scores (respectively beta=−2.0, beta=−3.5;both p=.04).

Conclusions—LGCC may improve outcomes among patients with elevated baseline cardiometabolic risk from community-based practices.

Keywords

Mood disorders bipolar; cardiovascular disease; self-management; recovery

BACKGROUND

Mental disorders are associated with premature mortality, primarily from cardiovascular disease (1). Cardiometabolic indicators, notably obesity, are key drivers of cardiovascular disease, which can be exacerbated by psychiatric symptoms such as depression and unhealthy behaviors including physical inactivity, overeating, and tobacco use (2).

As one of the most expensive mental disorders in the U.S. (3), bipolar disorder affects up to 6.4% of the U.S. population (4) and is characterized by alternating manic/depressive episodes that can lead to non-adherence, disrupted continuity of care, and elevated cardiometabolic risk (5). Many persons with bipolar or other mental disorders receive care from community-based mental health programs with limited access to medical care (6).

To date most programs that target cardiometabolic risk in mental disorders have primarily been implemented for unipolar depression (7) or involved intensive behavioral interventions (8). With the increasing focus on value-based care, practical interventions that address multiple cardiometabolic risk factors and can be taught to existing providers are desired by community-based providers.

Collaborative/chronic care models (9–10) potentially address multiple cardiometabolic risk factors among patients with mental disorders (7). These models usually consist of patient education on disease self-management, ongoing coordination of medical and mental health care by a non-physician interventionist, and ongoing symptoms monitoring (measurement-based care), and represent a core component of the emerging health home models in Medicaid programs (11). However, there has been limited implementation of chronic care models in community-based mental health programs, and none that have focused on bipolar disorder.

The goal of this pilot study is to determine whether a Chronic Care Model, Life Goals Collaborative Care (LGCC) compared to enhanced treatment as usual reduces cardiometabolic risk factors and improves outcomes for patients with bipolar disorder.

METHODS

This randomized controlled effectiveness trial compared LGCC to enhanced treatment as usual and enrolled patients diagnosed with bipolar disorder and had at least one cardiometabolic risk factor. The study was reviewed and approved by the University of Michigan Medical School Institutional Review Board.

Patients >=18 years from two community-based mental health outpatient programs in Southeastern Michigan were recruited in 2009 and randomized to receive LGCC or enhanced treatment as usual. Patients were included if they had an active diagnosis or treatment plan for Bipolar I, Bipolar II, or Bipolar NOS based on chart review; had at least one cardiometabolic risk factor (diagnosis or indication of hypertension, hyperlipidemia, diabetes, or BMI >25 based on medical record review), were community-dwelling, and English-speaking. Patients were excluded if they had severe cognitive impairment or were unable to give informed consent.

After a survey coordinator confirmed eligibility, patients provided informed consent and completed a clinical exam (weight, height, and two blood pressure measures) and a self-completed survey. Participants were compensated $10 for each assessment. A chart review was also conducted to ascertain utilization information. The data analyst then randomized participants to LGCC or enhanced treatment as usual in blocks of 16–20 stratified by age, race, and diabetes diagnosis in order to ensure balance of these characteristics. The survey

coordinator was blinded to randomization of patient assignment. Those randomized to LGCC were contacted by the study interventionist within two weeks to schedule intervention sessions.

LGCC intervention details are described elsewhere (12). In brief, the MSW-level interventionist provided four 2-hour weekly group self-management sessions, followed by brief care management contacts to patients randomized to LGCC for up to 6 months. Each group session included approximately 8–10 participants, and sessions were based on social cognitive theory. The sessions included active discussions by patients that were focused on their personal goals, and alignment of those goals with healthy behavior changes and action planning to cope with current symptoms. Specific focus points covered throughout the four sessions included bipolar disorder and cardiovascular disease risk, stigma issues, wellness habits including diet and exercise within the context of symptom coping strategies, and collaborative care management.

After the group sessions, the interventionist made brief (20-minute), individualized telephone or in-person contacts to patients over a 6-month period to track symptoms as well as progress towards wellness goals using motivational enhancement techniques. The interventionist tracked patient symptoms and health goals using an electronic registry over the 6-month period and alerted providers regarding medical or mental health needs.

The interventionist underwent a 2-day training program developed by the investigators and followed a standardized set of protocols and intervention manual. Fidelity was measured using a combination of direct observation of a random sample of Life Goals group sessions and reviews of interventionist logs. Key fidelity indicators included number of group sessions completed by the patient, number of focus points covered by the interventionist in the sessions, and number of follow-up contacts.

Enhanced TAU included monthly receipt of mailings on wellness topics over the course of the 6-month LGCC intervention period in addition to available mental health care, and referral to primary care services off-site.

Outcomes included cardiometabolic risk (body mass index-BMI, systolic/diastolic blood pressure), health-related quality of life (SF-12) (12), functioning (World Health Organization Disability Assessment Scale) (13), and psychiatric symptoms (Internal State Scale) (14)

Statistical analyses ascertaining the effect of LGCC versus enhanced treatment as usual were considered exploratory as this was a pilot study. Repeated measures analyses were used to determine the effect of LGCC versus enhanced treatment as usual on outcomes and utilization.

RESULTS

Out of 118 patients approached, 12 were ineligible due to not having a confirmed bipolar diagnosis, 13 were ineligible due to not having a cardiometabolic risk factor, and 25 declined to participate. There were no significant differences among those who declined

versus those who were enrolled. Of the 68 enrolled, 34 were randomized to LGCC and 34 to enhanced treatment as usual. Overall, 65 completed 6 and 12-month assessments. The mean age was 45±13, with 61% female, and 19% African-American (Table 1). The majority of participants had elevated cardiometabolic risk factors at baseline, notably hypertension, high BMI, and diabetes. Twenty-six percent had a current prescription for a mood stabilizer, and 11% for an atypical antipsychotic medication (Table 1).

Among the LGCC group, 26 (79%) completed >=3 self-management sessions, the interventionist covered >80% of session focus points, and the mean number of follow-up contacts completed was 4.5±1.5 out of 6. The mean number of contacts to providers made by interventionists for each patient was 2.2±1.8 during the 6-month follow-up period.

Repeated measures analyses (Table 2) found that LGCC compared to enhanced treatment as usual was not associated with reduced cardiometabolic risk factors or improved health-related quality of life. Only the effects of LGCC on reduced impaired functioning and on depressive symptoms approached significance, with effect sizes of, respectively, .20 and .23.

In a repeated measures post-hoc analysis in which the sample was limited to those with elevated cardiometabolic risk, those with BMI >=30 or systolic blood pressure of >=140 in the LGCC compared to the enhanced treatment as usual group had decreased impaired functioning (respectively beta=−2.2, beta=−3.8; both p=.04) and depressive symptom scores (respectively beta=−2.0, beta=−3.5; both p=.04) (See Appendix). However, after Bonferoni adjustment, these findings are not statistically significant. Further, we conducted a multifactorial analysis with treatment and groups as factors included in the repeated measure multivariate regression models, and test the interactions between treatment and groups. The results showed a significant interaction between treatment and SBP>=140 groups(beta for the interaction=−4.1, p=0.02), indicating the LGCC decreased impaired functioning more so in the SBP>=140 group than the SBP<140 group; however, there was no interactions between the treatment and BMI>=30 groups in the impaired functioning model, and no significant interactions were found in the depression symptom model. Wherein these post-hoc analyses are for exploratory purpose, the significant interactions between the treatment and SBP>=140 warrants further investigations on what characteristics-bearing groups may benefit the most out of the LGCC intervention.

There were no significant differences in utilization between the LGCC and enhanced treatment as usual groups over the 12-month study period, and 40% of the overall sample received diet and wellness group sessions apart from LGCC (See Appendix).

DISCUSSION

Compared to enhanced treatment as usual, LGCC was not associated with reduced cardiometabolic risk factors or other patient outcomes. However, among patients with elevated cardiometabolic risk, LGCC resulted in reduced impaired functioning and depressive symptoms.

LGCC was designed to be cost-efficient, emphasizing patient self-management, and care management was limited to communication with clinicians as opposed to medication

management. Available medical care was off-site, which may have impeded access to cardiometabolic risk factor management. Katon et al. (7) found that the chronic care model led to reduced cardiometabolic risk primarily through medical care management for patients with substantial medical burden. In contrast, LGCC involved four 2-hour self-management sessions and limited follow-up contacts with providers, which may have had limited impact on cardiometabolic risk in our sample. Our target population included those with a wider range of cardiometabolic risk factors, which may have led to little room for improvement in outcomes. Moreover, “usual care” in our community mental health programs included group wellness sessions which might have mitigated any differences in cardiometabolic risk in the LGCC group.

Nonetheless, LGCC improved outcomes for patients with elevated cardiometabolic risk (high BMI or elevated blood pressure), notably reduced impaired functioning and depressive symptoms. Previous studies of the chronic care model for bipolar disorder did not find significant reductions in depression (15). Perhaps LGCC’s focus on health behavior strategies had a positive effect on depression and functioning. Reducing depressive symptoms and functional impairment could also be initial steps in ultimately reducing cardiometabolic risk, by mitigating barriers to self-management strategies such as exercise. Interventions that focus on improved functioning are also important given that they help with recovery-oriented goals such as employment and relationships.

The elevated risk of mortality due to cardiovascular disease has been well-recognized among persons with mental disorders (2). To date there have been few effective interventions to improve outcomes in this group that are also practical to implement in community-based settings. Recognizing the mortality gap due to cardiovascular disease among persons with mental disorders, community-based mental health programs have advocated for integrated general medical services. The Substance Abuse and Mental Health Services Administration funded several demonstration programs focused on improving medical outcomes among patients seen in community mental health programs. The Affordable Care Act has also proposed health home models that reimburse medical care for persons with mental disorders. Still, these initiatives have not specified the types of services that should be provided, or how to integrate and reimburse for components of the chronic care model such as self-management.

Limitations of this study included the relatively small sample size and lack of formal diagnostic assessment for bipolar disorder. The limited use of care management beyond the group sessions may have explained the limited impact of LGCC on long-term cardiometabolic risk. Only a fraction of participants had complete lab data (e.g., lipids, glucose), which may have reflected inadequate access to medical care, and we were unable to specify the types of medical care provided. As some mental health providers likely had patients from both study conditions, the contacts they received from the interventionists may have also affected the likelihood that they would apply more careful cardiometabolic monitoring to those in the enhanced treatment as usual group. Finally, the study’s findings may not generalize to settings outside of Southeastern Michigan.

Nonetheless, as a relatively brief intervention emphasizing self-management, LGCC may lead to increased daily, social, and occupational functioning and reduced depressive symptoms among the most medically vulnerable. Ultimately, psychosocial interventions such as LGCC have potential to improve outcomes that are consistent with recovery-oriented care, and can inform the emerging medical home models for persons with mental disorders. Further research is needed to determine whether LGCC can impact cardiometabolic risk factors across a broad group of individuals with mental disorders, either through enhanced self-management over the long term and/or through more intensive medical care management. Whether LGCC can be applied to improve cardiometabolic outcomes in other treatment settings such as primary care would also be helpful in further tailoring these programs to help the most vulnerable.

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Table 1

Patient Baseline Characteristics: Life Goals Collaborative Care (LGCC) Vs. Enhanced Treatment as Usual

	Total (N= 65)		**LGCC (N=32)**		**Enhanced Treatment as Usual (N=33)**				
Demographics	**Mean±SD**		**Mean±SD**		**Mean±SD**		**T**	**df**	**p**
Age M ± SD	45.3±12.8		47.2±11.8		43.4±13.6		−1.20	63	.24
	N	**%**	**N**	**%**	**N**	**%**	**Chi-sq**		**p**
Female	39	61	18	56	21	66	.59	1	.44
African-American	12	19	7	22	5	16	.34	1	.56
Some college education	41	64	22	71	19	58	1.25	1	.26
Current Illicit Substance Use	17	27	8	27	9	28	.02	1	.90
Current smoker	33	54	15	50	18	58	.40	1	.53
Medication and Health Services Use	**N**	**%**	**N**	**%**	**N**	**%**	**Chi-sq**		**p**
Any mood stabilizer prescription[a]	17	26	10	31	7	21	.85	1	.36
Any atypical antipsychotic prescription[a]	7	11	3	9	4	12	.13	1	.72
Insurance type									
Medicaid	13	28	8	33	5	22	7.67	3	.06
Medicare	12	26	6	25	6	26			
Medicaid&Medicare	16	34	10	42	6	26			
Other insurance	6	13	0	0	6	26			
Outcomes-Baseline Values									
BMI, kg/m^2	35.2±7.3		33.2±6.2		37.2±7.9		2.28	63	.03
Waist Circumference, inches	45.0±6.0		42.7±5.4		47.3±5.8		3.33	63	.01
Systolic Blood Pressure, mmHg	133.9±1.7		130.2±13.3		137.5±24.1		1.52	63	.13
Diastolic Blood Pressure, mmHg	85.1±11.1		84.0±10.0		86.2±12.1		.78	63	.44
Quality of Life[b]									
SF-12 MCS	29.9±6.9		30.1±7.4		29.7±6.4		−.20	63	.84
SF-12 PCS	35.8±8.2		34.8±7.7		36.8±8.7		.89	63	.38

	Total (N= 65)		LGCC (N=32)		Enhanced Treatment as Usual (N=33)				
Demographics	**Mean±SD**		**Mean±SD**		**Mean±SD**		**T**	**df**	**p**
Functioning[c]	18.8±8.7		16.7±9.6		20.9±7.4		1.96	63	.06
Symptoms[d]									
Depressive	8.8±6.3		7.8±6.5		9.9±6.0		1.40	63	.17
Manic	18.7±12.8		16.4±14.3		21.0±10.9		1.43	63	.16

[a] Any current mood stabilizer prescription included Lithium, valproate, carbamazepine, or lamotrigine. Any atypical antipsychotic use included olanzapine, ziprasidone, aripiprazole, quetiapine, clozapine, or ziprazidone

[b] Health-related quality of life (SF-12) includes a mental health (MCS) and physical health component score (PCS). Possible scores range from 0 to 100, with higher scores indicating better health scores. For both summary scores, the population M ± SD is 50 ± 10.

[c] Impaired functioning was assessed using the World Health Organization Disability Assessment Scale, a 12 item measure that assesses the degree of functional impairment experienced over the past month regarding self-care, mobility, cognition, social functioning, and role functioning, with possible scores ranging from 0 to 48 (higher scores indicating worse functioning).

[d] Symptom scores were based on the Internal State Scale, an 8-item assessment of depressive and manic symptoms that are strongly correlated with clinician ratings. For depressive symptoms, possible scores range from 0 to 20. For manic symptoms, possible scores range from 0 to 50, Higher score indicate more severe symptoms.

Table 2

Repeated Measures Analysis: 12-Month Outcomes Comparing Life Goals Collaborative Care (LGCC) Versus Enhanced Treatment as Usual

	LGCC						Enhanced Treatment as Usual						Repeated Measures Analysis[d]					
N=65	**Baseline**		**6 month**		**12 month**		**Baseline**		**6 month**		**12 month**		**Beta**	**95% CI**	**T**	**df**	**P**	**D[e]**
Cardiometabolic Risk	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**						
BMI	33.2	6.1	32.8	6.7	32.6	5.5	37.2	7.9	36.6	9.2	36.5	10.4	−.03	−0.9, 0.9	−.1	62	.95	−.04
Waist circumference, in	42.7	5.4	43.9	7.1	43.0	6.2	47.3	5.8	48.7	7.3	46.7	6.3	−.29	−1.4, 0.9	−.5	62	.61	−.05
Blood pressure-systolic mmHg	130.2	13.3	134.9	13.1	134.5	17.5	137.5	24.1	132.8	15.8	135.3	19.0	−.54	−4.7, 3.6	−.3	62	.79	−.02
Blood pressure-diastolic mmHg	84.0	10.0	84.9	12.3	83.2	12.7	86.2	12.1	84.6	13.2	84.1	11.7	−.84	−3.9, 2.2	−.6	62	.58	−.07
Quality of Life[a]																		
SF-12 MCS	30.1	7.4	32.5	7.4	33.2	5.5	29.7	6.4	31.5	7.9	31.0	6.6	.03	−1.9, 1.9	.03	51	.98	.01
SF-12 PCS	34.8	7.7	34.8	7.0	36.0	8.8	36.8	8.7	35.5	7.2	34.3	7.1	.85	−1.1, 2.8	.9	51	.38	.12
Functioning[b]	17.3	9.5	16.8	8.0	15.7	11.8	20.9	7.4	19.9	6.1	21.2	7.5	−1.35	−3.0, 0.3	−1.6	59	.11	−.20
Symptoms[c]																		
Depressive	7.8	6.5	6.4	6.0	5.4	5.1	9.9	6.0	9.0	6.3	8.8	6.7	−1.15	−2.7, 0.4	−1.5	61	.15	−.23
Manic	17.5	14.1	17.0	14.7	16.6	16.0	21.5	10.6	20.6	12.2	18.0	10.1	−.64	−3.7, 2.5	−.4	59	.68	−.07

[a] Health-related quality of life (SF-12) includes a mental health (MCS) and physical health component score (PCS). Possible scores range from 0 to 100, with higher scores indicating better health scores. For both summary scores, the population M ± SD is 50 ± 10.

[b] Impaired functioning was assessed using the World Health Organization Disability Assessment Scale, a 12 item measure that assesses the degree of functional impairment experienced over the past month regarding self-care, mobility, cognition, social functioning, and role functioning, with possible scores ranging from 0 to 48 (higher scores indicating worse functioning).

[c] Symptom scores were based on the Internal State Scale, an 8-item assessment of depressive and manic symptoms that are strongly correlated with clinician ratings. For depressive symptoms, possible scores range from 0 to 20. For manic symptoms, possible scores range from 0 to 50, Higher score indicate more severe symptoms.

[d] Repeated measures analysis adjusted for the baseline value of the outcome, effect of the Life Goals Collaborative Care (LGCC), time (6, 12 months), and the interaction of time and LGCC effect.

[e] Cohen's D is a measure of effect size, with D >.3 indicating small to moderate effect